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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,972	06/15/2000	Ada Goerlach-Graw	BMID 9941 US	8671

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	PAPER NUMBER
1641	9

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/594,972	Applicant(s) GOERLACH-GRAW ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-42* is/are pending in the application.

4a) Of the above claim(s) *27-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Claims 27-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

2. Applicant's election with traverse of claims 15-26 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the method of Group II and the device of Group I are disclosed as usable together and that the search required for group II does not present an additional burden on the examiner, thus, applicant argues that restriction is improper. This is not found persuasive. The devices of Groups I and III are different because the device of Group III does not require a material that enables liquid transport between the zones. Because the two devices are deemed to be different, therefore, even though the method of Group II may be used with the device of Group I, the two inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Group II can be practiced with another materially different product, such as the device of Group III. Finally, the kit of Group IV does require neither the device of Group I nor the device of Group III. Because the inventions are distinct and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes is proper. Further, the search required for Group I is not required for Groups II-IV, therefore, it would pose undue burden to search and examine all groups together.

3. The requirement is still deemed proper and is therefore made FINAL.

Specification

4. Applicant is reminded of the proper content of an abstract of the disclosure.

5. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

6. Extensive mechanical and design details of apparatus should not be given.

7. The abstract of the disclosure is objected to because it is not a concise statement of the invention. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

8. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

9. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

10. Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is confusing with respect to the recitation "an impregnated conjugate" because it is unclear what this means. In general, "impregnated" implies loading a carrier of some sort with a material that causes the carrier to be full. In the instant case, an impregnated conjugate may be interpreted as a conjugate comprising at least two different species conjugated together, and the conjugate is further loaded with a third species. Such a conjugate is not supported by the specification. Further, the specification does not describe the "impregnated conjugate" in such a way as to clearly identify the different components of such a conjugate.

Claim 15 is also confusing with respect to the recitation of "a second bioaffine binding partner capable of a specific binding reaction with the first detectable label and a second detectable label". It is unclear where the second detectable label is located. Is it on the second bioaffine binding partner? If so, this should be made clear.

Claim 20 is confusing because the recitation of "the second bioaffine binding partner is an antibody to digoxigenin or digoxin" lacks antecedent support.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 15-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick et al (US 5,451,504) in view of Decker et al (US 4,230,683).

Fitzpatrick discloses a device and method for detecting the presence and amount of an analyte in a sample. The device of Fitzpatrick comprises a chromatographic strip having a sample contact zone, a trapping zone, and a detection zone. The sample contact zone contains mobilizable, labeled-receptor to the analyte. The trapping zone contains immobilized ligand (analyte or analyte analog) that will bind free receptor moving through the trap zone. And, the detection zone contains immobilized receptor that will bind the labeled-receptor/analyte complex enabling their detection therein. See columns 4-9 and figure 1. Fitzpatrick teaches labels such as colloidal gold or colored latex particles for use in the device. See column 8, lines 30-48.

Fitzpatrick differs from the claimed invention in failing to teach a universal conjugate.

Decker, however, teaches an improved method for detecting antigen by reacting a hapten-labeled antibody with the antigen, and then reacting the hapten moiety with a second, labeled anti-hapten antibody, and determining the amount of label bound to a solid support as a measure of the amount of the antigen in a sample. Decker teaches haptens such as digoxin as appropriate for use in the hapten-labeled antibody. See column 1, lines 19-32, and lines 55-68. Decker teaches that the hapten-labeled antibody provides the advantages of amplifying the antigenicity of the bound antibody, thus, enabling an increased in binding of the antibody to the antigen. See column 2, line 34 through column 3, line 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Fitzpatrick by using the hapten-labeled method of Decker. Such a modification provides the advantage of amplifying the antigenicity of the bound antibody thereby increasing the sensitivity of the assay as taught by Decker. Further, a skilled artisan would have had a reasonable expectation of success in using the hapten-labeled antibody of Decker in the device of Fitzpatrick because such modification is a mere alternative and functionally equivalent labeling technique that is well known in the art. See Decker, column 1, lines 5-32. Additionally, since only the expected labeling effect would have been obtained, the use of alternative and functionally equivalent labeling techniques, such as taught by Decker, would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Claims 18, 19 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick in view of Decker as applied to claims 15-17 and 20-23 above, and further in view of Bernstein et al (US 5,824,268).

See the discussion of Fitzpatrick and Decker above. These references differ from the claimed invention in failing to teach an elution agent application zone located upstream of the sample application zone.

Bernstein, however, discloses a test device comprising a series of bibulous strips having a buffer zone, a sample zone, a reaction zone and a detection reagent zone, consecutively (column 6, lines 24-67). Bernstein teaches that the disclosed device provides the advantages of a simple test device where all the reagents, including liquid phase solvents, buffers, etc, necessary to perform the assay are incorporated and requiring only the additional of test sample. The placement of the various zones allows the appropriate addition of reagents and improves the assay results because the presence of the analyte can be determined in a sequential form of immunoassay. And, because all reagents are flowing simultaneously, the assay time will be shorter for any given result.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device of Fitzpatrick as modified by Decker to include a buffer addition zone upstream of the sample addition zone such as taught by Bernstein. The inclusion of such a buffer addition zone provides the advantages of a simple test device where all the reagents, including liquid phase solvents, buffers, etc, necessary to perform the assay are incorporated and requiring only the additional of test sample. Further, Bernstein teaches that the placement of the various zones allows the appropriate addition of reagents and improves the assay results because the presence of the analyte can be determined in a sequential form of immunoassay. And, because all reagents are flowing simultaneously, the assay time will be shorter for any given result.

A skilled artisan would have had a reasonable expectation of success in modifying the device of Fitzpatrick to include a buffer addition zone as taught by Bernstein because Fitzpatrick teaches that more than three zones may be included in it's device (Fitzpatrick, column 3, lines 27-37), and Bernstein teaches that it is advantageous to include all reagents necessary for an assay in one test device (Bernstein, column 3, lines 28-38).

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday - Wednesday from 9:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641

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January 23, 2002